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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,970	05/03/2006	Yukiko Sugihara	06303/HG	7540

1933 7590 08/14/2009  
FRISHAUF, HOLTZ, GOODMAN & CHICK, PC  
220 Fifth Avenue  
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NEW YORK, NY 10001-7708

EXAMINER
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LAU, JONATHAN S

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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08/14/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/577,970	<b>Applicant(s)</b> SUGIHARA ET AL.	
	<b>Examiner</b> Jonathan S. Lau	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-27 is/are pending in the application.
- 4a) Of the above claim(s) 9-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3 pgs / 09 Apr 2009</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action is responsive to Applicant's Amendment and Remarks, filed 03 Jun 2009, in which claims 1, 6 and 8 are amended to change the scope and breadth of the claim; claim 4 is canceled and withdrawn claims 9 and 19 are amended.

This application is the national stage entry of PCT/JP04/17031, filed 10 Nov 2004; and claims benefit of foreign priority document JAPAN 2003-380194, filed 10 Nov 2003; currently an English language translation of this foreign priority document has not been made of record.

Claims 1-27 are pending in the current application. Claims 9-27, drawn to non-elected inventions, are withdrawn. Claims 1-3 and 5-8 are examined on the merits herein.

### ***Drawings***

The drawings as originally filed on 03 May 2006 are acknowledged and accepted.

### ***Information Disclosure Statement***

The information disclosure statement filed 09 Apr 2009 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most

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knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered as indicated by the specific references lined through and not initialed. The initialed references have been considered as indicated.

### ***Objections Withdrawn***

Applicant's Amendment, filed 03 Jun 2009, with respect to objections to claims 6-8 as being in improper form has been fully considered and is persuasive, as amended claims 6 and 8 are not multiple dependent claims that depend from another multiple dependent claim. Claim 7 depends from claim 6 and incorporates all limitations therein, including amendments to the scope and breadth of the claim. Claims 6-8 are herein treated on the merits.

This objection has been **withdrawn**.

Applicant's Amendment, filed 03 Jun 2009, with respect to objections to claims 1-5 for informalities as reciting the phrase "comprising polysaccharide and water as essential components" has been fully considered and is persuasive, as amended claims 1-5 clearly recite the transitional phrase "comprising".

This objection has been **withdrawn**.

### ***Rejections Withdrawn***

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Applicant's Amendment, filed 03 Jun 2009, with respect to all grounds of rejection of claim 4 has been fully considered and is persuasive, as claim 4 is canceled.

All rejections of claim 4 have been **withdrawn**.

Applicant's Amendment, filed 03 Jun 2009, with respect to claims 1-5 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been fully considered and is persuasive, as claim 1 as amended recites polysaccharides that are described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 03 Jun 2009, with respect to claims 1-5 rejected under 35 U.S.C. 112, first paragraph, as not reasonably providing enablement for the full scope of all polysaccharides has been fully considered and is persuasive, as claim 1 as amended recites polysaccharides that are described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention and Applicant's remarks are persuasive that sufficient direction or guidance is presented for the scope of the scope of the invention as claimed.

This rejection has been **withdrawn**.

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Applicant's Amendment, filed 03 Jun 2009, with respect to claims 1-4 rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al. (Cereal Chemistry, 1975, 52, p70-78, of record) with evidence of inherent properties is provided by the Merck Index (entry for Dextrin-Maltose, Merck Index, of record) has been fully considered and is persuasive, as Johnson et al. discloses a solution of a maltooligosaccharide and amended claim 1 does not encompass maltooligosaccharides.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 03 Jun 2009, with respect to claims 1-5 rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (Cereal Chemistry, 1975, 52, p70-78, cited in PTO-892) has been fully considered and is persuasive, as Johnson et al. teaches a solution of a maltooligosaccharide and amended claim 1 does not encompass maltooligosaccharides.

This rejection has been **withdrawn**.

Applicant's Amendment and Remarks, filed 03 Jun 2009, with respect to claims 1-5 provisionally rejected on the ground of nonstatutory double patenting over claims 1-16, 50, 51 and 52 of copending Application No. 10/486122 has been fully considered and is persuasive with regard to claims 4 and 5, as instant claim 4 is canceled and claims 1-6 of copending Application No. 10/486122 are canceled.

This provisional rejection with regard to claims 4 and 5 has been **withdrawn**.

This provisional rejection with regard to claims 1-3 is modified as recited below.

The following are new or modified grounds of rejection necessitated by Applicant's Amendment, filed 03 Jun 2009, in which claims 1, 6 and 8 are amended to change the scope and breadth of the claim and claim 4 is canceled. Claim 7 depends from claim 6 and incorporates all limitations therein, including amendments to the scope and breadth of the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Amended Claims 1-3 and 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Inohara et al. (WIPO Publication WO 2003/013612, published 20 Feb 2003, provided by Applicant in IDS mailed 03 May 2006). As this document is in Japanese, US Patent Application Publication 2004/0266725 (of record) is provided as an English language equivalent and is referred to as Inohara et al. herein.

Inohara et al. discloses a composition containing a polysaccharide in water (abstract). Inohara et al. discloses a composition containing the 0.1 wt % of the polysaccharide agar in water (page 2, paragraph 26), meeting limitations of instant claims 1-3 and 8. Inohara et al. discloses said composition useful for application to an ocular mucous membrane in the form of a topically applied eyedrop with excellent characteristics (page 6, paragraph 62), implicitly meeting all structural limitations of the

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intended use of being “operable to be uniformly dispersed on a mucous membrane when topically administered to a mammal” and “wherein the mucous membrane is an ocular mucous membrane” of instant claims 6 and 7.

Inohara et al. is silent as to the amount of precipitated polysaccharide after performing centrifugal separation at 25 °C with 40,000x g for one hour. However, it is apparent from what is disclosed that this property is inherent to the identical chemical composition disclosed by Inohara et al. Products of identical chemical composition can not have mutually exclusive properties, see MPEP 2112.01 II. It is noted that *In re Best*, 562 F.2d 1252, 195 USPQ 430 (C.C.P.A. 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (C.C.P.A. 1980) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph).

**Response to Applicant's Remarks:**

Applicant's Remarks, filed 03 Jun 2009, have been fully considered and found not to be persuasive.

Applicant notes that Inohara et al. is drawn to a liquefied polysaccharide comprising gel particles providing drug retention, whereas the instant invention relates to a polysaccharide sol. However, the invention of Inohara et al. provides agar obtained in the state of a liquid composition not in the state of a gel (page 2, paragraph 26)



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having a low viscosity during storage (page 3, paragraph 36) and giving a liquid composition without gelling (page 4, paragraph 48 and page 7, paragraph 73).

Therefore, there is sufficient reason to believe the invention of Inohara et al. inherently includes the property of the amount of precipitated polysaccharide after performing centrifugal separation at 25 °C with 40,000x g for one hour being less than 65 wt% or 30 wt% of the total polysaccharide content. Applicant has provided no evidence that the subject matter shown to be in the prior art does not possess the characteristic relied on.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Amend Claims 1-3 are provisionally rejected on the ground of nonstatutory double patenting over amended claims 6-11 and 13-16 of copending Application No.

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10/486122, published as US Patent Application Publication 2004/0266725 cited in the 102(b) rejection above. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Claims 6-11 and 13-16 of copending Application No. 10/486122 are drawn to a composition comprising a polysaccharide, such as agar, and water.

The claims of copending Application No. 10/486122 are silent as to the amount of precipitated polysaccharide after performing centrifugal separation at 25 °C with 40,000x g for one hour. However, it is apparent from what is disclosed that this property is inherent to the identical chemical composition claimed in copending Application No. 10/486122. Products of identical chemical composition can not have mutually exclusive properties, see MPEP 2112.01 II. It is noted that *In re Best*, 562 F.2d 1252, 195 USPQ 430 (C.C.P.A. 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (C.C.P.A. 1980) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

**Response to Applicant's Remarks:**

Applicant's Remarks, filed 03 Jun 2009, have been fully considered and found not to be persuasive.

As this is not the only remaining grounds of rejection, it is proper to maintain this provisional rejection.

Amended Claims 1-3 and 5-8 are provisionally rejected on the ground of nonstatutory double patenting over amended claims 1-3 and 5-13 of copending Application No. 11/810524. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Amended Claims 1-13 of copending Application No. 11/810524 are drawn to a composition comprising a polysaccharide agar and water wherein the agar is in an amount from 0.1 wt% (claim 1) and 0.2 (claim 5).

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The claims of copending Application No. 11/810524 are silent as to the amount of precipitated polysaccharide after performing centrifugal separation at 25 °C with 40,000x g for one hour. However, it is apparent from what is disclosed that this property is inherent to the identical chemical composition claimed in copending Application No. 11/810524. Products of identical chemical composition can not have mutually exclusive properties, see MPEP 2112.01 II. It is noted that *In re Best*, 562 F.2d 1252, 195 USPQ 430 (C.C.P.A. 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (C.C.P.A. 1980) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

**Response to Applicant's Remarks:**

Applicant's Remarks, filed 03 Jun 2009, have been fully considered and found not to be persuasive.

As this is not the only remaining grounds of rejection, it is proper to maintain this provisional rejection.

***Conclusion***

No claim is found to be allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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